

K192358 Pressure Therapy System PT1003Apr 23, 2020
238 days to decisionK192358 · Product code: **IRP** · Physical Medicine
Source: <https://www.510kdatabase.net/k192358/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Powered Inflatable Tube (IRP)
Date received	Aug 29, 2019
Decision date	Apr 23, 2020
Days to decision	238 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Xiamen Senyang Co., Ltd.
Location	Xinglin Xiamen, CN
Contact	Nina Cai
510(k) history	3 submissions · 3 cleared · 2017-2020

REGULATORY CONSULTANT

Consulting firm	Shanghai Sungo Management Consultanting Co., Ltd.
Contact	Raymond Luo

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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